



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM12/0108

FOLEY AND LARDNER  
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SUITE 500  
WASHINGTON DC 20007-2696

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/050,991	03/31/98	014	EPPS, J	1635 01/08/01
First Named Applicant	GETZENBERG, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION RENAL NUCLEAR MATRIX PROTEINS, POLYNUCLEOTIDE SEQUENCES ENCODING THEM, AND THEIR USE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
1 76333/150	530-358.000	A34	UTILITY	YES	\$620.00	04/09/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

PATENT AND TRADEMARK OFFICE COPY

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	09/050,991	GETZENBERG, ROBERT H.
	Examiner Janet L Epps	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Amendment C and Examiner's Amendment & Interview 12-15-00.
  2.  The allowed claim(s) is/are 16, 17, 21, 40, 42, 43 and 48-55.
  3.  The drawings filed on \_\_\_\_\_ are acceptable as formal drawings.
  4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
    - a)  All
    - b)  Some\*    c)  None    of the:
      1.  Certified copies of the priority documents have been received.
      2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5.  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).
- Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**
6.  Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
  7.  Applicant MUST submit NEW FORMAL DRAWINGS
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review( PTO-948) attached
      - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
    - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
    - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.**

8.  Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

#### Attachment(s)

- |   |  |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>16</u> . |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>12/2</u> | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                       |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material    | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                 |
|   | 9 <input type="checkbox"/> Other   |

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#16/  
D  
12-15-00  
JL**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

2. On the first line of the specification the following phrase is inserted This  
D1  
application claims benefit under 35 USC 119(e) of provisional application 60/041,860,  
filed April 8, 1997.—

Claim 1 is cancelled in favor of newly added claim 55.

D2  
Claims 4-15, 18-20, 22-39, and 44-47, drawn to a non-elected invention without  
traverse in Paper #8, are cancelled.

D3  
2 16. (Amended Twice) A method for detecting a cell proliferative disorder in a subject,  
comprising contacting a cellular component from the subject with a reagent which binds  
to a cellular component associated with a nuclear matrix protein of [claim 1] claim 55[.],  
wherein the expression of said nuclear matrix protein indicates the presence or absence  
of said cell proliferative disorder.

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Claim 40, all instances of the term "function" are deleted and replaced with the term --expression--; additionally the term "claim 1" is deleted and replaced with the term --claim 55--.

Claim 41 is cancelled, since this claim does not further limit amended claim 40.

Claims 48-53, line 1, the phrase "or an antigenic fragment thereof" is deleted.

The following new claims are added.

14 54. The method of claim 16, wherein the reagent is an antibody that binds to said nuclear matrix protein.

13 55. A purified nuclear matrix protein (NMP), wherein said NMP is selected from the group consisting of:

- (a) RCCA-1 having a molecular weight of about 53 kD and a pI of about 9.30,
- (b) RCCA-2 having a molecular weight of about 32 kD and a pI of about 6.95,
- (c) RCCA-3 having a molecular weight of about 27 kD and a pI of about 6.50,
- (d) RCCA-4 having a molecular weight of about 20 kD and a pI of about 5.25,
- (e) RCCA-5 having a molecular weight of about 15 kD and a pI of about 6.00, and
- (f) RCNL-1 having a molecular weight of about 103 kD and a pI of about 8.30.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

jle  
December 29, 2000

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER

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**ATTACHMENT TO AND MODIFICATION OF**  
**NOTICE OF ALLOWABILITY (PTO-37)**  
***(November, 2000)***

**NO EXTENSIONS OF TIME ARE PERMITTED TO FILE  
CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE  
OATH OR DECLARATION, notwithstanding any indication to the  
contrary in the attached Notice of Allowability (PTO-37).**

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored<sup>1</sup>:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. ~~Extensions of time may be obtained under the provisions of 37 CFR 1.136(a)~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

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<sup>1</sup> The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See "Changes to Implement the Patent Business Goals", 65 Fed. Reg. 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 Off. Gaz. Pat. Office 77, 99, 110, 135, 139 (September 19, 2000).